

# UNITED STATES PATENT AND TRADEMARK OFFICE

In re Janssen Pharmaceutica N.V.  
Request for Patent Term Extension  
U.S. Patent No. 4,631,278

:  
: **ORDER GRANTING**  
: **INTERIM EXTENSION**

On June 17, 1999, Janssen Pharmaceutica N.V., the owner of record in the United States Patent and Trademark Office of U.S. Patent No. 4,631,278, filed an application under 35 U.S.C. § 156, requesting an extension of three years. The original expiration date of the patent is August 1, 2004. The patent claims the active ingredient diclazuril of the animal drug product "CLINACOX®," and the method of use of said product. The application indicates, and the Food and Drug Administration has confirmed, that the product has undergone a regulatory review under Section 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) before the first permitted commercial use or sale of the product.

Review of the application indicates that the subject patent is eligible for an extension of the patent term under 35 U.S.C. § 156. Since it is apparent that processing of the application for patent term extension will not be completed before the date of expiration of the patent, interim extension of the patent term is appropriate.

An interim extension under 35 U.S.C. § 156(e)(2) of the term of U.S. Patent No. 4,631,278 is granted for a period of one year from the original expiration date of the patent, until August 1, 2005.

Date

7/28/04

Jon W. Dudas

Acting Under Secretary of Commerce for Intellectual Property and  
Acting Director of the United States Patent and Trademark Office